DEC 2 9 2011

510(k) Summary of Safety and Effectiveness
LDR Spine USA Cervical Interbody Fusion System

Owner's Name & Address:	LDR Spine USA 13785 Research Boulevard, Suite 200 Austin, TX 78750 Phone: (512) 344-3333 Fax: (512) 344-3350
Contact Person:	Kiersten Soderman Regulatory Affairs Specialist LDR Spine USA 13785 Research Boulevard, Suite 200 Austin, TX 78750 Phone: (512) 344-3370 Fax: (512) 344-3350 Email: kierstensoderman@ldrspine.com
Date:	November 29, 2011
Common Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical (OVE) Intervertebral Fusion Device with Bone Graft, Cervical (ODP)
Classification:	OVE, ODP- 21 CFR 888.3080- Intervertebral Body Fusion Device
Proprietary Name:	LDR Spine Cervical Interbody Fusion System- ROI-C Lordotic Implants
Legally Marketed Predicate Device:	LDR Spine Cervical Interbody Fusion System K091088
Device Description	The ROI-C Lordotic implant is an extension of the currently cleared ROI-C cervical interbody fusion system and is intended for use as an interbody fusion device in the cervical spine. The device is manufactured from medical grade PEEK OPTIMA® LT1 in accordance with ASTM F2026 and has tantalum markers conforming to ASTM F136

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embedded in the implant extremities to facilitate visibility in x-ray imaging. The subject device is designed for placement using an open anterior approach.

Indications for Use:

The LDR Spine Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2–T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The LDR Spine ROI-C Cervical Interbody Fusion System is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

Non-Clinical

Testing included Finite Element Analysis simulating static axial compression and static axial torsion (per ASTM F2077). The results of this testing demonstrate that the performance of the ROI-C Lordotic implant, when compared with its legally marketed predicates, is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 9 2011

LDR Spine USA
% Ms. Kiersten Soderman
Regulatory Affairs Specialist
13785 Research Boulevard, Suite 200
Austin, Texas 78750

Re: K113559
Trade/Device Name: LDR Spine Cervical Fusion System – ROI-C Lordotic Implants
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: November 30, 2011
Received: December 01, 2011

Dear Ms. Soderman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K113559

Device Name: LDR Spine Cervical Interbody Fusion System- ROI-C Lordotic Implants

Indications for Use:

The LDR Spine Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2–T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The LDR Spine ROI-C Cervical Interbody Fusion System is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113559